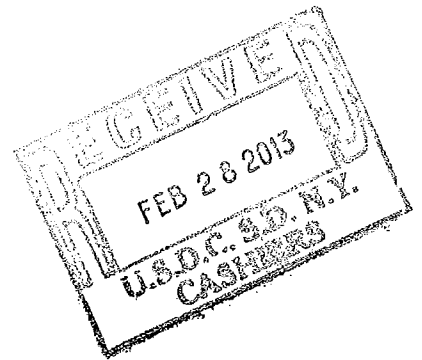


Gerald G. Paul (GP-1450)
Grant A. Shehigian (GS-0904)
FLEMMING ZULACK WILLIAMSON ZAUDERER LLP
One Liberty Plaza, 35th Floor
New York, New York 10006
212-412-9500
gpaul@fzwz.com
gshehigian@fzwz.com
Attorneys for Plaintiffs
ABBVIE INC. and
ABBVIE BIOTECHNOLOGY LIMITED

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
202-408-4000
Of Counsel for Plaintiffs

13 CV 1358



UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ABBVIE INC. and
ABBVIE BIOTECHNOLOGY LIMITED,

Plaintiffs,

v.

THE KENNEDY TRUST FOR
RHEUMATOLOGY RESEARCH,

Defendant.

Civil Action No. _____
ECF Case

COMPLAINT

Plaintiffs AbbVie Inc. (f/k/a Abbott Laboratories) and AbbVie Biotechnology Limited (f/k/a Abbott Biotechnology Limited) (collectively "AbbVie") bring this action against The Kennedy Trust for Rheumatology Research (f/k/a The Mathilda and Terence Kennedy Institute of Rheumatology Research) ("Kennedy") for a declaratory judgment that the claims of

Kennedy's U.S. Patent Nos. 8,298,537 ("the '537 patent") and 8,383,120 ("the '120 patent") are invalid and that AbbVie does not and will not owe royalties to Kennedy for those patents. A true and correct copy of the '537 patent is attached as Exhibit A. A true and correct copy of the '120 patent is attached as Exhibit B.

NATURE OF ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

PARTIES

2. Plaintiff AbbVie Inc. is a Delaware corporation that has a principal place of business in Illinois and conducts business in this District. AbbVie Inc. is engaged in the development, sale and distribution of a broad range of pharmaceutical and biologic drugs.

3. Plaintiff AbbVie Biotechnology Limited is a corporation organized under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. Through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff AbbVie Biotechnology Limited.

4. In 2003, Abbott Laboratories and its affiliates (collectively "Abbott") began marketing in the United States its highly acclaimed HUMIRA[®] product, an inventive human, high-affinity and neutralizing "anti-TNF α " antibody. In January 2013, Abbott Laboratories spun off its AbbVie affiliate. Since January 2013, AbbVie markets and sells HUMIRA[®] throughout the United States. Since 2003, HUMIRA[®] has been used to treat hundreds of thousands of patients who suffer from various TNF-related conditions, including rheumatoid arthritis.

5. Defendant Kennedy is organized and exists under the laws of the United Kingdom, having a place of business at 26-28 Hammersmith Grove, Hammersmith, London W6 8LH England and a registered office at 16 St. John's Lane London EC1M 4BS England. Defendant Kennedy is the owner of certain United States patents, including the '537 and '120 patents-in-suit, as well as United States Patent Nos. 7,846,442 ("the '442 patent," a true and correct copy of which is attached as Exhibit C) and 6,270,766 ("the '766 patent," a true and correct copy of which is attached as Exhibit D).

6. In 2002, Abbott obtained a license to Kennedy's '766 patent and related intellectual property, and since that time has made quarterly payments to Kennedy under the agreement. In January 2013, AbbVie assumed Abbott's licensing responsibilities to Kennedy.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 and 28 U.S.C. §§ 2201 *et seq.*

8. As noted above, Abbott (or its successor, AbbVie) has been marketing and selling HUMIRA® in the United States since early 2003. AbbVie has no plans to cease such activities.

9. Abbott (or its successor, AbbVie), having paid royalties for many years under the now-expired '766 patent, reasonably expected that its royalty obligations would have ended upon expiration of the '766 patent in October 2012.

10. On January 26, 2011, however, counsel for Kennedy sent a letter to Abbott notifying it of the issuance of the '442 patent on December 7, 2010, and asserting that pursuant to its existing license obligations "Abbott will owe royalties to Kennedy" under the '442 patent through August

21, 2018. While the amount of royalties Abbott was paying under the license was unchanged at that time, the issuance of the '442 patent purportedly extended Abbott's obligation to pay royalties pursuant to the license by almost six years. Specifically, Kennedy contended that Abbott must pay royalties through the '442 patent's August 2018 expiration date, rather than cease payments when the '766 patent expired in October 2012.

11. Because Kennedy's '442 patent is invalid for obviousness-type double patenting over Kennedy's '766 patent, Abbott brought suit against Kennedy in this Court on April 13, 2011, seeking a declaratory judgment that the '442 patent is invalid. *Abbott Laboratories v. The Mathilda & Terence Kennedy Instit. of Rheumatology Trust*, No. 11-cv-02541-PAC (S.D.N.Y. Apr. 13, 2011) ("the '442 action").

12. Kennedy moved to dismiss the '442 action for lack of subject matter jurisdiction on grounds that it "fail[ed] to satisfy the 'case-or-controversy' requirement of Article III of the U.S. Constitution" and that "any dispute about the payment of royalties is subject to mandatory arbitration." ('442 action, D.I. 19 at 1.)

13. This Court denied Kennedy's motion to dismiss the '442 action, ruling that an actual controversy existed between the parties that was "both immediate and real." ('442 action, D.I. 25 at 11.)

14. In denying Kennedy's motion, this Court held that Kennedy's January 26, 2011, letter "put[] Plaintiffs on notice that it intends to enforce its new patent and expects Plaintiffs to continue paying royalties on their existing sublicensing agreement for another six years," that "Defendant has a history of enforcing its patent rights against third parties," and that "[i]n light

of the totality of the circumstances, it is objectively reasonable to believe that the Defendant intends to enforce its patent rights over its '442 patent." ('442 action, D.I. 25 at 6.)

15. This Court also held that challenges to patent validity were not governed by the license's arbitration clause, and that if Abbott were to terminate or breach the license agreement, Abbott would face an infringement action and/or an action to enforce the license agreement by Kennedy. ('442 action, D.I. 25 at 7-8.)

16. Because "Plaintiffs should not be required to terminate its sublicensing agreement or otherwise bet the farm . . . before seeking a ruling on [] validity," ('442 action, D.I. 25 at 10 (internal quotation marks and citation omitted)), the Court denied Kennedy's motion to dismiss the '442 action.

17. Subsequently, the '442 action proceeded through discovery and additional motions by the parties, and was ultimately tried to the bench in September 2012. The parties' dispute over the '442 patent remains active and the corresponding declaratory judgment action is still pending.

18. While the '442 action was proceeding, Kennedy continued to seek additional patents stemming from the same family as the '766 and '442 patents. These patents would also fall under AbbVie's license.

19. On October 30, 2012, just over a month after trial of the '442 action, Kennedy obtained the '537 patent, and on December 14, 2012, counsel for Kennedy sent a letter to Abbott enclosing a copy of the '537 patent.

20. On February 6, 2013, the Patent and Trademark Office ("PTO") published a notice that Kennedy's '120 patent would shortly issue.

21. Both the '537 and '120 patents expire on August 1, 2016, almost four years after the expiration of the '766 patent.

22. AbbVie should no longer owe royalties to Kennedy pursuant to the parties' license obligations because the '766 patent has expired, and because the '537 and '120 patents (like the '442 patent) are invalid, at least for obviousness-type double patenting over Kennedy's '766 patent.

23. On February 12, 2013, AbbVie's counsel sent a letter to Kennedy's counsel asserting that Kennedy's '537 and '120 patents were invalid for the same reasons as the '442 patent, and asking Kennedy to confirm that it would dispose of any alleged payment obligations AbbVie would otherwise have under the '537 and '120 patents if the Court holds the '442 patent to be invalid.

24. On February 19, 2013, Kennedy's counsel responded by letter. Kennedy did not agree to AbbVie's request or suggest that AbbVie would not be required to pay royalties under the '537 or '120 patents, and instead referred to Abbott's royalty obligations set forth in the license agreement.

25. On February 26, 2013, the PTO issued Kennedy's '120 patent.

26. Under the totality of the circumstances, an actual controversy that is both immediate and real, and is sufficient to establish declaratory judgment jurisdiction with respect to the '537 and '120 patents, exists between AbbVie and Kennedy.

27. Kennedy has demonstrated through the '442 action, its correspondence with AbbVie, and its history of enforcing its patent rights that, despite expiration of the '766 patent, Kennedy

intends to seek royalties from AbbVie for many more years by enforcing its recently-issued continuation patents. AbbVie would risk an infringement action if it terminated the license agreement or an action to enforce the license agreement if it breached the license agreement.

28. Kennedy refused to agree to AbbVie's contention that the parties' rights would be determined by any decision by this Court in the '442 action.

29. On information and belief, Kennedy exploits its patents only by enforcing them via judicial or extra-judicial means (i.e., having no products of its own, Kennedy exploits its patents solely by licensing and enforcing them).

30. In addition to asserting its rights against AbbVie in the pending '442 action, Kennedy has filed other patent infringement actions concerning the '766 patent family against other parties when disputes have arisen. For example, in 2010, when a dispute arose as to royalties allegedly owed on Kennedy's '766 patent, Kennedy sued UCB Inc. for patent infringement. *See Mathilda & Terence Kennedy Instit. of Rheumatology Trust v. UCB, Inc.*, 2010-cv-00650 (D. Del.) (filed Aug. 3, 2010). Likewise, in 2009, Kennedy sued Amgen, Inc. and others for infringement of the '766 patent. *See Mathilda and Terence Kennedy Instit. of Rheumatology Trust v. Amgen Inc. et al.*, 2009-cv-00805 (D. Del.) (filed Oct. 27, 2009). In 2008, when Abbott and Kennedy disputed the proper method for calculating the royalty amounts owed pursuant to their '766 patent licensing obligations, Kennedy initiated an arbitration against Abbott. Kennedy also filed six counterclaims in the '442 action relating to royalty disputes between the parties under the '766 license agreement.

31. This Court has personal jurisdiction over Kennedy. On information and belief, Kennedy conducts its patent licensing and enforcement activities through its New York patent counsel.

On information and belief, these attorneys have accepted service of process on behalf of Kennedy in prior litigation. These New York attorneys also sent Abbott and AbbVie the above-referenced communications regarding Kennedy's continuation patents.

32. The agreement under which AbbVie pays royalties to Kennedy is governed by New York law. Previous disputes under the agreement have been litigated and arbitrated in New York, and Kennedy did not object to personal jurisdiction in any of these actions. Nor did Kennedy dispute personal jurisdiction in this District with respect to the pending litigation on the '442 patent.

33. Moreover, in addition to the pending '442 action in this Court, Kennedy initiated an arbitration pursuant to the parties' license agreement against Abbott in New York concerning the proper method for calculating the royalties owed on Kennedy's '766 patent. Kennedy and the parties to that arbitration later consented to having a judge in New York (in this District) confirm that arbitration award. *Abbott Biotechnology Ltd. v. The Mathilda & Terence Kennedy Instit. of Rheumatology Trust*, No. 09-cv-03872-DC (S.D.N.Y. Apr. 29, 2009). A litigation relating to this Kennedy arbitration also took place in and was resolved by this District. *See, e.g., Centocor, Inc. v. The Kennedy Instit. of Rheumatology*, No. 08-cv-08824, 2008 WL 4725036 (S.D.N.Y. Oct. 29, 2009) (Chin, J.). In November 2003, Kennedy and Abbott representatives met in New York to address issues with respect to licensing Kennedy's '766 patent and related intellectual property.

34. Kennedy has also granted its New York patent attorneys power of attorney to prosecute its patents before the PTO, including the '537 and '120 patents-in-suit, as well as Kennedy's '766 and '442 patents. And Kennedy's New York attorneys did in fact prosecute and obtain

those patents for Kennedy, and they remain the primary contact for all future correspondence from the PTO.

35. Venue lies in this District pursuant to 28 U.S.C. § 1391(b). And this case is related to *Abbott Laboratories v. The Mathilda & Terence Kennedy Instit. of Rheumatology Trust*, No. 11-cv-02541-PAC (the '442 action) currently pending in this district, to which the Court has devoted substantial time and resources.

FACTUAL BACKGROUND

The Parties' Licensing Relationship

36. Defendant Kennedy is the owner of the now-expired '766 patent, issued by the PTO on August 7, 2001. As more fully described below, the '766 patent relates to methods for treating arthritis and other diseases by "co-administering" methotrexate and an anti-TNF α antibody.

37. On January 1, 1992, Kennedy entered into a licensing agreement with a Pennsylvania corporation, Centocor, Inc. (now Janssen Biotech Inc., "Centocor"). Among other things, the agreement granted Centocor the right to sublicense Kennedy patent rights. On December 23, 2002, Centocor entered into a sublicense agreement with Abbott for Kennedy's '766 patent and related intellectual property.

38. On July 29, 2004, Centocor and Kennedy entered into an amendment of their 1992 agreement. Among other things, the amendment recognized the 2002 Centocor-Abbott sublicense agreement and allowed Abbott to pay royalties due thereunder directly to Kennedy.

39. In October 2008, this Court recognized (and Abbott and Centocor agreed) that Kennedy was an intended third-party beneficiary of Abbott's sublicense agreement with Centocor.

Centocor, Inc. v. The Kennedy Instit. of Rheumatology, No. 08 cv-08824, 2008 WL 4726036, at *3 (S.D.N.Y. Oc. 29, 2008) (“Here, it is undisputed that Kennedy is the intended third-party beneficiary of the [2002] Centocor-Abbott Agreement . . .”).

40. Based on the December 2002 sublicense agreement, Abbott has paid over one hundred million dollars in royalties for Kennedy’s now-expired ’766 patent. As noted above, Abbott’s licensing responsibilities to Kennedy were transferred to AbbVie in January 2013.

Kennedy’s ’766 Patent

41. Kennedy’s ’766 patent issued from U.S. patent application no. 08/690,775 (for convenience, “the ’766 application”), filed on August 1, 1996.

42. During prosecution of the ’766 application, Kennedy sought and was granted the benefit of an earlier filing date (or “priority”) for the ’766 patent’s “co-administration” claims. In particular, Kennedy successfully argued for priority, pursuant to 35 U.S.C. § 120 based on U.S. patent application no. 07/958,248 (“the ’248 application”), filed on October 8, 1992.

43. The ’766 patent expired on October 8, 2012, 20 years after the filing date of the ’248 application.

44. The ’766 patent issued with 30 claims. Claims 1-7 and 28-30 are directed to methods of treating arthritis. Claims 8-14 are directed to methods of treating rheumatoid arthritis. Claims 15-21 are directed to methods of treating Crohn’s disease. The remaining claims are directed to compositions used to carry out the methods. Claim 8 recites: “A method of treating rheumatoid arthritis in an individual in need thereof comprising co-administering methotrexate and an

antitumor necrosis factor alpha antibody or an antigen-binding fragment thereof to the individual, in therapeutically effective amounts.” Ex. D at col. 35, lines 59-63.

45. According to the ’766 patent, “[a]s a result of Applicants’ invention, a method is provided herein for treating and/or preventing a TNF-mediated disease in an individual, comprising co-administering methotrexate and a tumor necrosis factor antagonist to the individual in therapeutically effective amounts.” *Id.* at col. 4, lines 41-45.

46. In a September 1999 submission to the PTO, Kennedy characterized the ’766 patent invention as “the discovery that a TNF α antagonist can be administered to patients suffering from a TNF-mediated disease (such as an autoimmune or inflammatory disease) as adjuvant or concomitant therapy to methotrexate therapy.”

47. To overcome the PTO’s rejections concerning the patentability of the claimed invention, Kennedy pointed to allegedly “unexpected” results reported in the patent specification concerning the use of an anti-TNF antibody as “adjunctive” therapy with methotrexate in patients whose arthritis was not controlled by methotrexate alone.

48. Responding in May 2000 to the PTO’s assertion that such “unexpected” results were only shown under the limited conditions of “particular patient populations and particular dosing regimens,” Kennedy stated:

There is no technical reason to believe that the synergistic effects exemplified in the specification by combination therapy with methotrexate and a TNF α antagonist is limited to a certain patient population. That is, there is no technical reason to believe that treatment with a combination of methotrexate and a TNF α antagonist, in accordance with Applicants’ teachings, would not yield the superior therapeutic effects described in the subject application. The superior therapeutic effects are due to the coadministration of methotrexate and a TNF α antagonist functionally

limited to therapeutically effective amounts, as described in the specification.

49. Following Kennedy's assertion that the purportedly "unexpected," "synergistic" and "superior" therapeutic results reported in the patent specification were representative of the methods claimed in the '766 patent, the PTO allowed the claims and issued the '766 patent.

Kennedy's '442 Patent

50. Kennedy's '442 patent issued from U.S. patent application no. 11/225,631 (for convenience, "the '442 application"), filed on September 12, 2005. The '442 application is from the same chain of applications that gave rise to the '766 patent.

51. During prosecution of the '442 application, despite having previously relied on the earlier October 1992 priority date during prosecution of the '766 application, Kennedy instead sought and was granted the benefit of a filing date (or "priority") for the '442 patent's claims that went back only to 1996. As a consequence, Kennedy obtained years of additional exclusivity for its '442 patent.

52. The '442 patent issued on December 7, 2010, and has a 20-year term starting from the filing date of the '766 application. With an additional 750 days of patent term adjustment granted by the PTO, the '442 patent will thus not expire until August 21, 2018.

53. The '442 patent issued with 22 claims, and is identical to the '766 patent except for its claims and priority date. All the claims of the '442 patent are directed to a method of treating an individual suffering from rheumatoid arthritis. Ex. C at cols. 35-36.

54. The methods claimed in the '442 patent are within the scope of, and obvious variants of, at least claims 1-14 of Kennedy's '766 patent.

55. For example, claim 14 of the '442 patent recites: "[a] method of treating an individual suffering from rheumatoid arthritis and already receiving methotrexate whose active disease is incompletely controlled comprising administering to the individual with methotrexate therapy a different composition comprising an anti-human tumor necrosis factor-a monoclonal antibody, wherein such administration reduces or eliminates signs and symptoms associated with the rheumatoid arthritis." *Id.* at col. 36, lines 10-17.

56. Kennedy's arguments to the PTO for the separate patentability of the claims of the '442 patent contradicted or ignored the arguments it made years ago during the prosecution of the '766 patent.

57. For example, although Kennedy asserted that the '442 patent's claims to "adjunctive" therapy in patients "whose active disease is incompletely controlled despite already receiving methotrexate" were "patentably distinct" from the '766 patent's claims, Kennedy had already relied on the purported "unexpected" effectiveness of the use of such therapy in earlier arguing to the PTO for the patentability of the '766 patent claims.

58. Indeed, despite its prior assertion to the PTO during prosecution of the '766 patent that any "combination" of methotrexate and a TNF α antagonist would yield the "superior therapeutic effects" described in the '766 patent, Kennedy argued in support of the '442 patent claims in a May 2010 submission to the PTO that "[t]he advantages obtained using the adjunctive therapy described in the pending claims are NOT obtained with other types of combination therapy."

59. Moreover, Kennedy pointed to the *same studies and results* it used to show “unexpected” and “synergistic” benefits of the methods claimed in the ’766 patent to argue for “unexpected” benefits of the methods claimed in the ’442 patent.

60. The patent laws do not allow Kennedy to prolong its period of patent exclusivity by obtaining new claims to the same invention or obvious variants of the same invention it claimed in the ’766 patent.

The ’442 Action

61. As noted above, Abbott brought suit against Kennedy in this Court on April 13, 2011, seeking a declaratory judgment that the ’442 patent is invalid for obviousness-type double patenting over the ’766 patent.

62. In the ’442 action, Kennedy repeated to this Court the arguments it had made during prosecution of the ’442 patent, again contradicting or ignoring the arguments it had made years ago during prosecution of the ’766 patent.

63. For example, in its Pretrial Memorandum, Kennedy argued that “it was far from obvious that adjunctive therapy as recited in the claims of the ’442 patent would provide the unexpected results that were obtained” and that “[a]s shown during examination of the application by the PTO, the unexpected results include vast improvement over prior treatment regimens.” (’442 action, D.I. 98 at 3, 14.)

64. But Kennedy admitted during trial of the ’442 action that the purported “sequential” coadministration data on which it relied to show unexpected results for “adjunctive” treatment in patients “whose active disease is incompletely controlled despite already receiving methotrexate”

as compared to other types of combination therapy was a “small sample size,” not “scientifically proven” and potentially an “artifactual” result. (*E.g.*, ’442 action, Trial Tr. 523:18-525:15, 569:19-572:10.)

65. And Kennedy also admitted during trial of the ’442 action that the purported “sequential” coadministration data on which it relied to show unexpected results for “adjunctive” treatment in patients “whose active disease is incompletely controlled despite already receiving methotrexate” as compared to other types of combination therapy was referred to in both the ’442 patent specification and the scientific literature as “monotherapy” or “antibody alone” rather than a type of coadministration. (*E.g.*, ’442 action, Trial Tr. 518:14-22, 562:5-7.)

66. In addition to the ’442 patent’s claim limitations to “adjunctive” therapy in an individual “whose active disease is incompletely controlled despite already receiving methotrexate,” Abbott presented evidence in the ’442 action regarding the obviousness of various other limitations of the ’442 patent’s claims over the ’766 patent’s claims and prior art.

67. Trial of the ’442 action was completed on September 21, 2012. A decision on the validity of Kennedy’s ’442 patent is pending.

Kennedy’s ’537 Patent-in-Suit

68. As noted above, while the ’442 action was proceeding Kennedy continued to seek additional patents from the PTO that stemmed from the same patent family as the ’766 and ’442 applications.

69. Kennedy's '537 patent was filed on January 13, 2012. The '537 patent issued from U.S. patent application no. 13/350,262 (for convenience, "the '537 application"). The '537 application is from the same chain of applications that gave rise to the '766 and '442 patents.

70. During prosecution of the '537 application (as in the course of prosecution of the '442 application), despite having previously relied on the earlier October 1992 priority date during prosecution of the '766 application, Kennedy instead sought and was granted the benefit of a filing date (or "priority") for the '537 patent's claims that went back only to 1996. As a consequence (and as with the '442 patent), Kennedy thus obtained years of additional exclusivity for its '537 patent, beyond that provided by the '766 patent.

71. During prosecution of the '537 application, the examiner rejected all of the '537 application's claims for obviousness-type double patenting over Kennedy's '442 and '766 patents. Kennedy did not argue the claims of the '537 application were patentably distinct from the claims of the '442 patent. Instead, Kennedy overcame the rejection over the '442 patent by submitting a terminal disclaimer that disclaimed any portion of the '537 patent's term that would extend beyond the expiration date of the '442 patent.

72. The '537 patent issued on October 30, 2012. With a 20-year term starting from the filing date of the '766 application, the '537 patent will not expire until August 1, 2016.

73. The '537 patent issued with 30 claims, and (like the '442 patent) is identical to the '766 patent except for its claims and priority date.

74. Like the '442 patent, all the claims in the '537 patent are directed to a method of treating an individual suffering from rheumatoid arthritis. Ex. A at col. 35-36.

75. For example, claim 1 of the '537 patent recites: "[a] method of treating an individual suffering from rheumatoid arthritis who still has active disease despite prior therapy with methotrexate comprising concomitantly administering with methotrexate therapy a different composition comprising an anti-tumor necrosis factor- α antibody or a tumor necrosis factor- α binding fragment thereof to the individual, wherein the anti-tumor necrosis factor- α antibody or fragment thereof (a) binds to tumor necrosis factor- α and (b) inhibits binding of tumor necrosis factor- α to tumor necrosis factor- α cell surface receptors, wherein such administration reduces or eliminates signs and symptoms associated with rheumatoid arthritis." *Id.* at col. 35, lines 1-13.

76. The claims of the '537 patent are substantially identical in scope to the claims of the '442 patent. A comparison of the '537 patent claims to the '766 patent claims and prior art is not substantively distinguishable from a comparison of the '442 patent claims to the '766 patent claims and prior art.

77. For example, the methods of administration and the particular patient populations encompassed by the claims of the '537 and '442 patents are the same. While the '442 patent claims "adjunctive" therapy in an individual "whose active disease is incompletely controlled despite already receiving methotrexate," the '537 patent claims "concomitant" therapy in an individual "who still has active disease despite prior therapy with methotrexate."

78. To support its '537 patent claims to "concomitant" therapy, Kennedy made the *same arguments* to the PTO as it made during the '442 action and to the PTO in support of its '442 patent claims to "adjunctive" therapy, again contradicting or ignoring the arguments it made years ago during prosecution of the '766 patent.

79. Indeed, just as Kennedy had argued in support of its '442 patent claims that the advantages of "adjunctive" therapy in patients "whose active disease is incompletely controlled despite already receiving methotrexate" "are NOT obtained with other types of combination therapy," Kennedy argued in support of the '537 patent claims in a July 5, 2012 submission to the PTO that:

The fact that patients suffering with active rheumatoid arthritis despite prior treatment with methotrexate could experience significant therapeutic improvement upon receiving concomitant therapy involving an anti-TNF α antibody to ongoing methotrexate would have been unprecedented

80. And Kennedy pointed to the *same studies and results* in support of its '537 patent claims to "concomitant" therapy as it did in support of its '442 patent claims to "adjunctive" therapy and its '766 patent claims to "co-administration." Kennedy did not present arguments to the patent office trying to distinguish the '442 patent claims from the '537 patent claims.

81. For essentially the same reasons that Abbott established in the '442 action that the '442 patent claims were invalid, the '537 patent claims are within the scope of, and obvious variants of, at least claims 1-14 of Kennedy's '766 patent.

82. As with the '442 patent, the patent laws do not allow Kennedy to prolong its period of patent exclusivity by obtaining new claims in the '537 patent that cover the same invention or obvious variants of the same invention it claimed in the '766 patent.

Kennedy's '120 Patent-in-Suit

83. Kennedy's '120 patent was filed on January 13, 2012. The '120 patent issued from U.S. patent application no. 13/350,065 (for convenience, "the '120 application"). The '120

application is from the same chain of applications that gave rise to the '766, '442, and '537 applications.

84. During prosecution of the '120 application (as in the course of prosecution of the '442 and '537 applications), despite having previously relied on the earlier October 1992 priority date during prosecution of the '766 application, Kennedy instead sought and was granted the benefit of a filing date (or "priority") for the '120 patent's claims that went back only to 1996. As a consequence (and as with the '442 and '537 patents), Kennedy thus obtained years of additional exclusivity for its '120 patent, beyond that provided by the '766 patent.

85. During prosecution of the '120 application (as in the course of prosecution of the '537 application), the examiner rejected all of the '120 application's claims for obviousness-type double patenting over Kennedy's '442 and '766 patents. Kennedy did not argue the claims of the '120 application were patentably distinct from the claims of the '442 patent. Instead, as in the course of prosecution of the '537 application, Kennedy overcame the rejection over the '442 patent by submitting a terminal disclaimer that disclaimed any portion of the '120 patent's term that would extend beyond the expiration date of the '442 patent.

86. The '120 patent issued on February 26, 2013. With a 20-year term starting from the filing date of the '766 application, the '120 patent will not expire until August 1, 2016.

87. The '120 patent issued with 19 claims, and (like the '442 and '537 patents) is identical to the '766 patent except for its claims and priority date.

88. Like the '442 and '537 patents, all the claims in the '120 patent are directed to a method of treating an individual suffering from rheumatoid arthritis. Ex. B at col. 34:61-36.

89. For example, claim 1 of the '120 patent recites: “[a] method of treating an individual suffering from rheumatoid arthritis who, despite prior treatment with methotrexate, still has active disease, defined as the presence of six or more swollen joints plus at least three of the following four secondary criteria: duration of morning stiffness \geq 45 minutes; \geq 6 tender or painful joints; erythrocyte sedimentation rate (ESR) \geq 28 mm/hour; and C- reactive protein (CRP) \geq 20mg/l, which comprises administering to the individual, adjunctively and/or concomitantly, (1) multiple doses of a recombinant anti-human tumor necrosis factor- α monoclonal antibody at intervals of weeks, which antibody (a) binds specifically to human tumor necrosis factor- α and (b) inhibits binding of human tumor necrosis factor- α to both p55 and p75 cell surface receptors and (2) multiple doses of methotrexate at intervals of a week or weeks, wherein the treatment reduces the individual's signs and symptoms by greater than fifty percent (50%) according to the Paulus criteria for a significant duration of time.” *Id.* at col. 34:61-35:12.

90. The claims of the '120 patent are substantially identical in scope to the claims of the '442 patent. A comparison of the '120 patent claims to the '766 patent claims and prior art is not substantively distinguishable from a comparison of the '442 patent claims to the '766 patent claims and prior art.

91. For example, the methods of administration and the particular patient populations encompassed by the claims of the '120 and '442 patents are the same. While the '442 patent claims “adjunctive” therapy in an individual “whose active disease is incompletely controlled despite already receiving methotrexate,” the '120 patent claims “adjunctively and/or concomitantly” treating an individual “who, despite prior treatment with methotrexate, still has active disease.”

92. Similarly, while the '120 patent claims administration of "multiple doses" of antibody at "intervals of weeks" and of methotrexate at "intervals of a week or weeks," the '442 patent claims administration of "multiple doses" of antibody and methotrexate at "an interval of a week or weeks."

93. To support its '120 patent claims to multiple dosing of antibody and methotrexate at weekly intervals, Kennedy made the *same arguments* to the PTO that it made during the '442 action in support of the '442 patent's claims to multiple dosing of antibody and methotrexate at weekly intervals.

94. Indeed, Kennedy argued in support of its '120 patent claims in an October 5, 2012 submission to the PTO that multiple dosing of antibody and methotrexate at weekly intervals worked to "blunts the HACA response" to the antibodies and "inhibit[] residual HACA activity," just as Kennedy had argued during the '442 action in support of its '442 patent claims that recurrent administration served to "blunt the HACA" and "inhibit ... residual HACA." (*E.g.*, '442 action, Trial Tr. 689:17-22.) Kennedy did not present arguments to the patent office trying to distinguish the '442 patent claims from the '120 patent claims.

95. For essentially the same reasons that Abbott established in the '442 action that the '442 patent claims were invalid, the '120 patent claims are within the scope of, and obvious variants of, at least claims 1-14 of Kennedy's '766 patent.

96. As with the '442 patent, the patent laws do not allow Kennedy to prolong its period of patent exclusivity by obtaining new claims in the '120 patent that cover the same invention or obvious variants of the same invention it claimed in the '766 patent.

COUNT 1

(Declaratory Judgment of Invalidity of the '537 Patent)

97. Plaintiff AbbVie re-alleges paragraphs 1-96 as if fully set forth herein.
98. An actual controversy pursuant to 28 U.S.C. §§ 2201 *et seq.* exists between Plaintiff AbbVie and Defendant Kennedy concerning the validity of the claims of Kennedy's '537 patent.
99. The claims of the '537 patent are invalid for failing to meet the requirements of patentability under the federal patent laws, at least for obviousness-type double patenting over Kennedy's '766 patent.
100. AbbVie warrants a declaratory judgment that the claims of the '537 patent are invalid.

COUNT 2

(Declaratory Judgment of Invalidity of the '120 Patent)

101. Plaintiff AbbVie re-alleges paragraphs 1-100 as if fully set forth herein.
102. An actual controversy pursuant to 28 U.S.C. §§ 2201 *et seq.* exists between Plaintiff AbbVie and Defendant Kennedy concerning the validity of the claims of Kennedy's '120 patent.
103. The claims of the '120 patent are invalid for failing to meet the requirements of patentability under the federal patent laws, at least for obviousness-type double patenting over Kennedy's '766 patent.
104. AbbVie warrants a declaratory judgment that the claims of the '120 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AbbVie respectfully requests the following relief:

- (a) a declaration that the claims of U.S. Patent Nos. 8,298,537 and 8,383,120 are invalid and a final judgment incorporating the same;
- (b) a "speedy hearing" on its declaratory-judgment action as authorized by Fed. R. Civ. P. 57;

(c) entry of equitable relief, including injunctive relief that enjoins Defendant and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from asserting or in any way claiming infringement of U.S. Patent Nos. 8,298,537 and 8,383,120

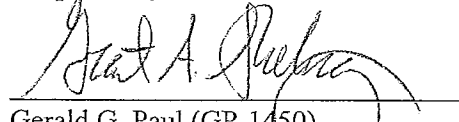
(d) a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding AbbVie its reasonable attorneys' fees, costs, and expenses;

(e) an order entitling AbbVie to recoup any and all royalty payments made for the period of time after the '766 patent expired, plus interest; and

(e) such other relief deemed just and proper.

Dated: February 28, 2013

Respectfully submitted,



Gerald G. Paul (GP-1450)

Grant A. Shehigian (GS-0904)

FLEMMING ZULACK WILLIAMSON

ZAUDERER LLP

One Liberty Plaza, 35th Floor

New York, New York 10006

(212) 412-9500

gpaul@fzwz.com

gshehigian@fzwz.com

Attorneys for Plaintiffs

ABBVIE INC.

ABBVIE BIOTECHNOLOGY LIMITED

Michael A. Morin

David P. Frazier

John T. Battaglia

Casey L. Dwyer (CD-7812)

FINNEGAN, HENDERSON, FARABOW

GARRETT & DUNNER, L.L.P.

901 New York Avenue, N.W.

Washington, D.C. 20001

(202) 408-4000

michael.morin@finnegan.com

david.frazier@finnegan.com

john.battaglia@finnegan.com

casey.dwyer@finnegan.com

Of Counsel for Plaintiffs

ABBVIE INC.

ABBVIE BIOTECHNOLOGY LIMITED